IJPSR (2022), Volume 13, Issue 7 **(Research Article)**

INTERNATIONAL JOURNAL OF PHARMACEUTICAL SCIENCES AND RESEARCH

Received on 27 October 2021; received in revised form, 16 December 2022; accepted, 05 May 2022; published 01 July 2022

DEVELOPMENT OF FLURBIPROFEN SODIUM ORAL DISINTEGRATING TABLETS BY DIRECT COMPRESSION AND SUBLIMATION TECHNIQUE

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Keywords:

Oral route, Sublimation, Thymol, Super disintegrant, SEM

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ABSTRACT: Objective: The present work aimed to prepare flurbiprofen tablets using different concentrations of super disintegrants like croscarmellose sodium, sodium starch glycolate cross povidone sublimating agent thymol. **Methods:** The tablets were prepared by direct compression and sublimation technique using different concentrations of super disintegrants. The prepared tablets were evaluated for different parameters like hardness, friability, weight variation, thickness, content uniformity, wetting time, disintegration time, and dissolution study. Morphology of pure drug and optimized formulation were revealed by using SEM. **Results:** All the formulations prepared with the highest concentration of super disintegrant showed the highest drug release. Formulations from F11 to F13 were prepared with the sublimation technique. F11 formulation showed the highest drug release because of its porous nature, which resulted from the sublimation technique. **Conclusion:** The optimized formulation of the sublimation method (F11) was porous in nature. *In-vitro* drug release of all formulations prepared with the highest concentration of super disintegrant showed higher drug release than lower concentrations. The formulations prepared by the sublimation technique showed good drug release compared to the direct compression method.

INTRODUCTION: Oral drug delivery is the most widely utilized route of administration among all the routes that have been explored for systemic delivery of drugs via pharmaceutical products of different dosage forms [1]. The oral route is considered as the most natural, uncomplicated, convenient, and safe due to ease of administration, patient acceptability, and cost-effective manufacturing process [2]. Orally disintegrating tablets immediately release the active drug when placed on the tongue, by rapid disintegration, followed by dissolution of the drug [3].

QUICK RESPONSE CODE

DOI: 10.13040/IJPSR.0975-8232.13(7).2703-09

This article can be accessed online on www.ijpsr.com

DOI link: http://dx.doi.org/10.13040/IJPSR.0975-8232.13(7).2703-09

The objective of this study was to formulate and evaluate tablets of flurbiprofen sodium by direct compression and sublimation technique. A propionic acid derivative, Flurbiprofen was a nonsteroidal anti-inflammatory agent (NSAID) with antipyretic and analgesic activity. Oral formulations of Flurbiprofen may be used for the symptomatic treatment of rheumatoid arthritis, osteoarthritis and ankylosing spondylitis [4]. In this study, various formulation trails of flurbiprofen sodium tablets were prepared using three super disintegrants: croscarmellose sodium, sodium starch glycolate, crospovidone and sublimating agent thymol.

All the tablets were subjected to drug-polymer interaction studies, weight variation, hardness, friability, disintegrating time, wetting time, drug content uniformity and *in-vitro* drug release and stability studies [5].

Hence, this combined approach was alternative for the preparation of the immediate-release tablets.

MATERIALS AND METHODS:

Materials: Flurbiprofen sodium (JP Fine chemicals, Pune), Microcrystalline cellulose (Degussa India Pvt. Ltd., Mumbai L. R), Croscarmellose (S. D. Fine Chem. Ltd., Mumbai. L. R), Sodium starch glycolate (S. D. Fine Chem. Ltd., Mumbai. L. R), Crospovidone (S. D. Fine Chem. Ltd., Mumbai. L. R), Thymol (S. D. Fine Chem. Ltd., Mumbai. L.R), Talc (Loba Chem. Pvt. Ltd., Mumbai, India), Magnesium Stearate (Degussa India Pvt. Ltd., Mumbai L. R), Aapartame (S. D. Fine Chem. Ltd., Mumbai. L. R), UV-Visible Spectrophotometer (Model UV- 2460, Lab India (UV-3000)), USP Type-II Dissolution Apparatus (Lab India (DS-8000)), Tablet punching machine-12 Stations (Remeik), FT-IR Spectrophotometer, FT-IR 200(Shimadzu Corporation, Japan), Scanning Electron Microscopy (JEOL JSM-6300) (Shimadzu Corporation, Japan).

Methods:

Preparation of Flurbiprofen Sodium Oral Disintegrating Tablets by Direct Compression Method: Oral dispersible tablets of Flurbiprofen sodium were prepared by using the direct compression method according to the formula given in table 1. Flurbiprofen sodium, crosscarmellose sodium /sodium starch glycolate /crospovidone, aspartame and microcrystalline cellulose are passed through sieve no 40 and blended it for 2 min. To this add magnesium stearate and talc which was previously passed through sieve no 60 and blend for 1 min [6]. Then compress the blend by using 9 mm punch [7]. The prepared tablets are evaluated for hardness, friability, weight variation, thickness, content uniformity, disintegration time, and dissolution study [8].

TABLE 1: FORMULATION DESIGN OF FLURBIPROFEN SODIUM DIRECTLY COMPRESSED TABLETS

Batch code	Flurbiprofen sodium (mg)	SSG (%)	CCS (%)	CP (%)	MCC (mg)	Magnesium state (mg)	TALC (mg)	Aspartame (mg)
F1	50	2	-	-	190	1.25	1.25	2.5
F2	50	4		-	185	1.25	1.25	2.5
F3	50	6			180	1.25	1.25	2.5
F4	50		2		190	1.25	1.25	2.5
F5	50	-	4		185	1.25	1.25	2.5
F6	50	-	6		180	1.25	1.25	2.5
F7	50	-	-	2	190	1.25	1.25	2.5
F8	50	-	-	4	185	1.25	1.25	2.5
F9	50	-	-	6	180	1.25	1.25	2.5
F10	50	-	-	-	195	1.25	1.25	2.5

Preparation of Flurbiprofen Sodium Porous Tablets by Sublimation Technique: Sublimed tablets of Flurbiprofen sodium tablets were prepared by sublimation technique.

The basic principle involved in the preparation of oral dispersible tablets by sublimation technique was addition of inert solid ingredients (thymol) were added to tablet excipients and the blend was compressed in to tablet [9]. The composition of formulations was given in **Table 2**. The drug mixed with other excipients like diluents, thymol, combination of thymol with super disintegrant and aspartame. To this add magnesium stearate and talc which was previously passed through sieve no 60 and blend for 1 min.

Then compress the above blend by using 9 mm punch [10]. After compression tablets were sublimated at 65^{o}C for 2 h. The prepared tablets are evaluated for hardness, friability, weight variation, thickness, content uniformity, wetting time, disintegration time and dissolution study [11].

TABLE 2: FORMULATION DESIGN OF FLURBIPROFEN SODIUM SUBLIMED TABLETS

Batch code	Flurbiprofen sodium (mg)	CCS (%)	Thymol (%)	MCC (mg)	Magnesium state (mg)	TALC (mg)	Aspartame (mg)
F11	50	2	4	177.5	2.5	2.5	2.5
F12	50	4	2	177.5	2.5	2.5	2.5
F13	50	-	6	177.5	2.5	2.5	2.5

RESULTS AND DISCUSSIONS: The granulation characteristics are the most important interest to formulation scientists and, therefore, most universally measured. These basic measurements of the granulation have been used to develop and monitor the manufacture of many successful pharmaceutical dosage forms [12]. Blend ready for compression containing drug and other excipients are subjected to pre-compression parameters (micrometric properties) to study its flow properties so as to achieve uniformity of tablet weight [13]. The results of pre-compressional parameters like bulk density, tapped density, compressibility index, and hausner's ratio are given in **Table 3**. Bulk density may influence compressibility, tablet porosity, dissolution, and other properties and depends on the particle size, shape, and tendency of particles to adhere together [14].

The bulk density and tapped density of powder blend of Flurbiprofen sodium was found to be between 0.452±0.015 to 0.484±0.039 and 0.521±0.023 to 0.649±0.019. The values of bulk density and tapped density lies within the acceptable range; from this the % compressibility of the powder can be calculated. Carr's index was found to be between 11.13 to 27.77. Hausner's ratio is a simple method to evaluate powder column stability and estimate flow properties. Hausner's ratio was found to be 1.126 to 1.385. A low range was observed in Hausner's ratio, which indicates good flowability [15]. The angle of repose of all the formulations was observed within the range of25.39±0.070 to 25.25±0102 to 29.28±0.061. All the formulations showed an angle of repose below $30^{o,}$ which indicates a good flow property.

TABLE 3: PRE-COMPRESSIONAL PARAMETERS OF DIRECT COMPRESSION AND SUBLIMED FORMULATIONS

Batch Code	Bulk density (gm/mL)	Tapped density (gm/mL)	Compressibility index (%)	Hausner's Ratio	Angle of Repose (°)
F1	0.452±0.015	0.564±0.039	19.85	1.24	29.28±0.061
F2	0.461±0.056	0.581±0.045	20.65	1.26	25.25±0.102
F3	0.472±0.010	0.649±0.010	27.27	1.372	26.75±0.056
F4	0.463±0.036	0.521±0.029	11.132	1.125	27.11±0.041
F5	0.471±0.048	0.548±0.058	14.05	1.163	28.19±0.010
F6	0.484±0.039	0.583±0.064	16.98	1.204	26.87±0.010
F7	0.465±0.047	0.573±0.044	18.84	1.232	27.56±0.032
F8	0.468±0.061	0.648±0.012	27.77	1.385	26.98±0.059
F9	0.478±0.060	0.604±0.019	20.86	1.263	25.99±0.061
F10	0.463±0.010	0.521±0.023	11.132	1.125	26.35±0.055
F11	0.468±0.062	0.648±0.025	27.27	1.385	25.68±0.069
F12	0.461±0.059	0.581±0.042	20.65	1.26	25.61±0.102
F13	0.472±0.034	0.649±0.019	27.77	1.32	26.45±0.049

The hardness values are in the range between 2.8±0.09 to 3.2±0.12 kg/cm^2 for directly compressed tablets and for sublimed tablets, ranging from 2.5±0.06 to 2.8±0.07 kg/cm ^{2}.

TABLE 4: POST-COMPRESSIONAL PARAMETERS OF DIRECTLY COMPRESSED AND SUBLIMED FLURBIPROFEN SODIUM TABLETS

Batch Code	Thickness (mm) ±SD (n=3)	Hardness (kg/cm^2) ±SD (n=3)	Friability (%) ±SD (n=20)	Average weight of the tablet (mg) (n=10)
F1	3.01±0.01	3.1±0.1	0.28±0.41	254.7±0.46
F2	3.06±0.01	2.9±0.09	0.18±0.23	251.6±0.41
F3	3.06±0.04	2.5±0.07	0.167±0.25	250.2±0.39
F4	3.06±0.02	3.0±0.07	0.14±0.22	248.8±0.35
F5	3.04±0.02	3.2±0.12	0.121±0.36	251.3±0.48
F6	3.06±0.03	2.9±0.13	0.141±0.19	249.2±0.29
F7	3.08±0.02	2.5±0.09	0.157±0.25	250.8±0.44
F8	3.08±0.03	2.8±0.09	0.114±0.34	251.2±0.36
F9	3.06±0.04	2.9±0.05	0.112±0.41	252.4±0.48
F10	3.03±0.03	2.8±0.08	0.132±0.36	252.2±0.27
F11	3.04±0.03	2.8±0.07	0.123±0.34	251.4±0.15
F12	3.03±0.02	2.8±0.04	0.142±0.25	250.2±0.21
F13	3.04±0.03	2.5±0.06	0.125±0.19	250.8±0.34

Tablet means thickness (n=3) was almost uniform in all the formulations, and values are ranged from 3.01±0.01mm to 3.08±0.002mm for directly compressed tablets, and for sublimed tablets ranged from 3.04±0.03mm to 3.04±0.03mm.

The standard deviation values indicated that all the formulations were within the range and showed uniform thickness.

TABLE 5: CONTENT UNIFORMITY OF VARIOUS FORMULATIONS OF FLURBIPROFEN SODIUM

Batch code	Drug content (%)
F1	97.047±0.367
F2	95.089±0.567
F3	101.052±0.284
F4	95.244±0.543
F5	98.001±0.768
F6	99.723±0.956
F7	95.762±0.823
F8	95.004±0.945
F9	99.12±0.881
F10	99.32±0.925
F11	97.11±1.25
F12	98.32±0.33
F13	99.21±0.89

Each values represents the mean ± SD n=6

All the prepared tablets comply with the Indian Pharmacopoeia standard for weight variation and friability **Table 4.** The drug content was found to be in the range of 95.002±0.945% to 101.05±0.284% for the tablets prepared both by sublimation and direct compression method **Table 5**. It indicates good content uniformity in all formulations. The wetting time studies of prepared porous tablets were performed in phosphate buffer at the pH of 6.8, and the results are presented as percentage weight change concerning time in hrs shown in **Table 6**. Different formulations have different wetting times; these are obtained by using various types and concentrations of superdisintegrants and sublimating agents for various formulations [16]. The directly compressed tablets with croscarmellose sodium showed less wetting time than the tablets containing cross povidone and sodium starch glycolate. The formulations prepared with croscarmellose and thymol showed less wetting time than those prepared with only croscarmellose sodium tablets.

TABLE 6: WETTING TIME PROFILES OF BOTH DIRECTLY COMPRESSED AND SUBLIMED TABLETS

F1 (sec)	F2 (sec)	F3 (sec)	F4 (sec)	F5 (sec)	F6 (sec)	F7 (sec)	F8 (sec)	F9 (sec)	F10 (sec)	F11 (sec)	F12 (sec)	F13 sec)
53 ±3	52 ±2	48 ±3.5	38 ±1.5	32 ±2.5	26 ±1.1	46 ±3.4	45 ±1.9	43 ±2.8	122± 1.4	18± 1.5	21± 2.7	62± 3.4

Disintegration time of various formulations were determined and values were showed in **Table 7** and **Fig. 1** and **2**, F11 formulation showed less disintegration time compared to all other formulations which was formulated by sublimation technique because of its porosity it disintegrates within seconds compared to the formulations prepared by direct compression method [17].

TABLE 7: DISINTEGRATION TIME (SEC) PROFILES OF FLURBIPROFEN SODIUM IN VARIOUS FORMULATIONS

F1	F2	F3	F4	F5	F6	F7	F8	F9	F10	F11	F12	F13
70± 3.2	65±2 .5	57±1 .8	52±2 .2	44±3 .1	38±1 .1	66±2 .4	65±1 .6	62±1 .9	161± 2.1	25± 1.4	38± 1.6	88.3±1 .3

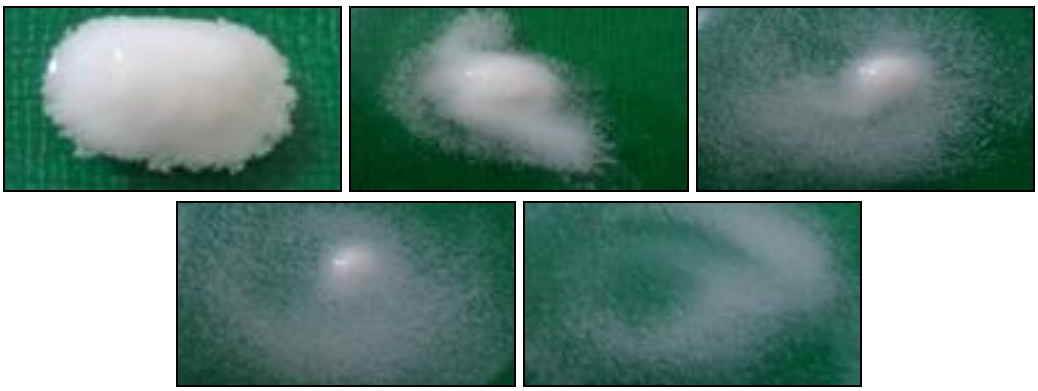

FIG. 1: DISINTEGRATION PATTERN OF F11

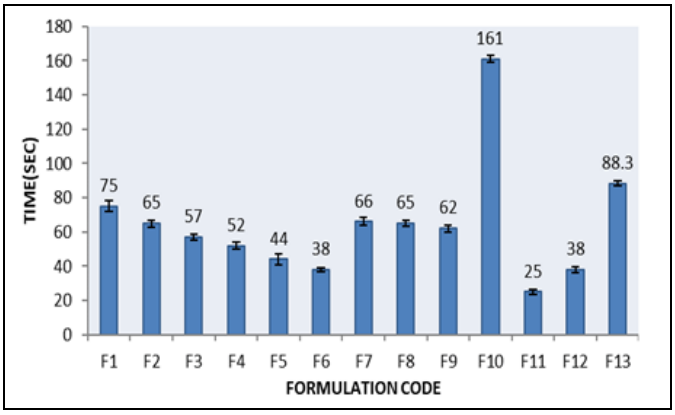

FIG. 2: DISINTEGRATION PROFILE OF VARIOUS FORMULATIONS

Drug release studies were carried out for both directly compressed and sublimed tablets of Flurbiprofen sodium by using USP type II (paddle) apparatus. 900 mL phosphate buffer pH 6.8 was used as dissolution medium, and the paddle was rotated at 60 rpm at temperature (37^{o}C ± 0.5^{o}C). After each sampling interval, sampling was done at regular intervals and replaced by fresh media. The samples are then analyzed spectrophotometrically at λ_{max} of the drug (*i.e* 247nm). In the case of the directly compressed Flurbiprofen sodium tablets, the effect of superdisintegrant on the drug release relatively to time was determined. In the case of sublimed tablets of Flurbiprofen sodium, the effect of super disintegrant and sublimating agent on the amount of drug release relatively to time was determined[18]. Experimentally the release rate of the formulation without any superdisintegrants (F10) was also studied in phosphate buffer pH 6.8 showed less amount of drug release than the sublimed and directly compressed tablets. Table 8 and **Fig. 3** and **4** summarize the % drug release from the directly compressed Flurbiprofen sodium tablets at various time intervals using sodium starch glycolate, cross caramellose sodium, and crospovidone as super disintegrants.

The % drug release values increased with an increase in the concentration of the sodium starch glycolate, cross caramellose sodium and cross povidone. The rapid increase in dissolution of sodium starch glycolate was may be due to rapid uptake of water by forming a gel layer, while tablets formulated with croscarmellose sodium disintegrated may be due to swelling and wicking action in primary particles and crospovidone containing tablets disintegrated may be due to its high capillary action and less tendency to gel formation [19].

TABLE 8: *IN-VITRO* DISSOLUTION PROFILE OF VARIOUS FORMULATIONS OF FLURBIPROFEN SODIUM

Batch Codes	5 min	10 min	20 min	30 min	40 min	50 min	60 min
F1	16.66	34.25	44.95	52.38	57.86	67.31	73.25
F2	23.23	44.8	57.57	65.24	68.61	72.55	77.01
F3	41.61	50.65	60.26	69.04	72.28	79.74	83.94
F4	16.97	35.1	44.33	54.878	69	76.53	81.8
F5	24.91	50.66	62.39	69.99	76.33	80.21	84.9
F6	32.75	56.47	64.3	78.58	84.84	87.13	89.4
F7	19.58	36.5	40.19	49.45	63.37	66.19	72.11
F8	30.73	39.36	48.02	61.46	70.89	76.66	79.83
F9	36.44	43.51	49.41	59.85	68.14	77.09	83.71
F10	6.33	9.53	13.43	17.22	20.51	22.34	25.32
F11	46.81	49.27	59.03	72.17	96.5	97.7	99.84
F12	52.12	57.7	61.91	75.96	83.64	93.7	98.91
F13	8.79	14.83	23.08	28.25	32.00	35.03	39.64

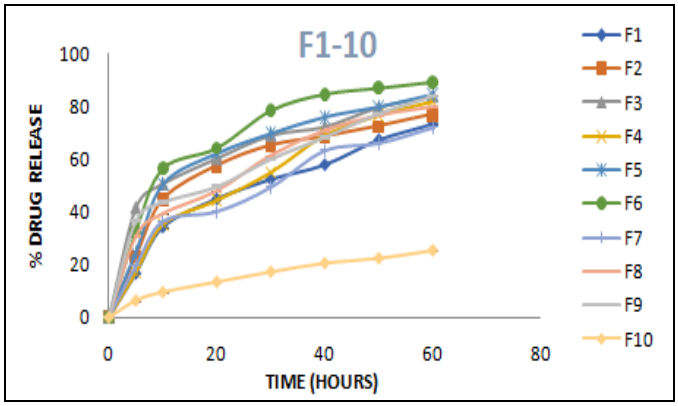

FIG. 3: CUMULATIVE DRUG RELEASE OF DIRECTLY COMPRESSED TABLETS

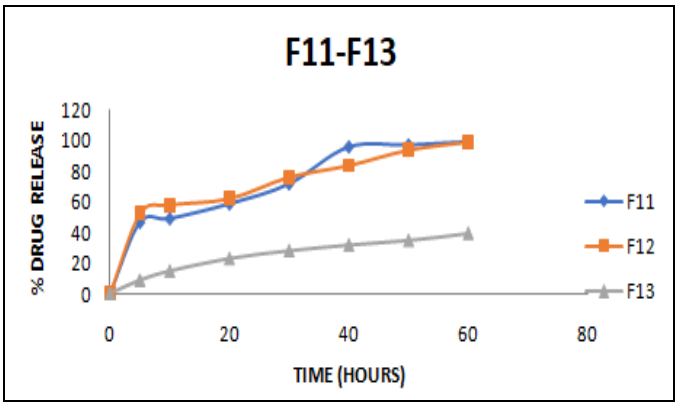

FIG. 4: CUMULATIVE DRUG RELEASE OF SUBLIMED TABLETS OF FLURBIPROFEN SODIUM

For the optimized formulation of prepared tablets, stability studies were conducted and showed in **Table 9** there was no changes were observed it indicating that the formulation was stable.

TABLE 9: STABILITY STUDIES OF F11 FORMULATION

Parameters	Intial 40°C / 75% RH	After 3 months at 40 °C/ 75% RH
Hardness	3.04±0.03	2.8±0.08
Drug content	97.11±1.25	96.34±1.49
Disintegration time	25±1.4	28±1.8
Drug release at end of 60min	99.84±1.2	95.32±2.7

Scanning Electron Microscopy: The scanning electron micrographs of pure Flurbiprofen sodium, and optimized formulation tablet are shown in the **Fig. 5A** and **5B,** respectively. Pure Flurbiprofen sodium appears as blunt crystals, with a smooth surface, shown in **Fig. 5A**. The optimized formulation of the sublimation method (F11) showed the formation of porous nature, which is responsible for rapid disintegration.

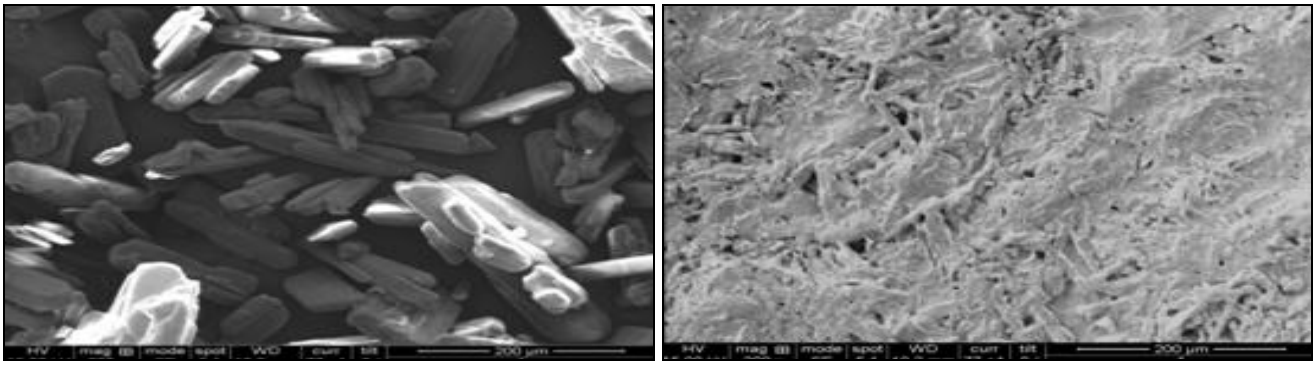

FIG. 5: SEM PICTURES (5A) PURE FLURBIPROFEN SODIUM, F11(5B) FORMULATION

CONCLUSION: The present work of this study was to formulate and evaluate porous tablets of flurbiprofen sodium by sublimation technique.

In this study, various formulation trails of flurbiprofen sodium tablets were prepared using three super disintegrants: crosscarmellose sodium, sodium starch glycolate, crospovidone, and sublimating agent thymol. All the tablets were subjected to drug-polymer interaction studies, weight variation, hardness, friability, disintegrating time, wetting time, drug content uniformity and *in-vitro* drug release and stability studies. Hence, this combined approach was an alternative for preparing the immediate-release tablets.

ACKNOWLEDGEMENT: The authors would like to thank St. Peters College of Pharmacy for providing all the requirements used in the dissertation work.

CONFLICTS OF INTEREST: No conflict of interest.

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How to cite this article:
Prabhakar MM and Rajitha K: Development of flurbiprofen sodium oral disintegrating tablets by direct compression and sublimination technique. Int J Pharm Sci & Res 2022; 13(7): 2703-09. doi: 10.13040/IJPSR.0975-8232.13(7).2703-09.

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